Charles M. Lizza
William C. Baton
Elina Slavin
SAUL EWING ARNSTEIN & LEHR LLP
One Riverfront Plaza, Suite 1520
Newark, New Jersey 07102-5426
(973) 286-6700
clizza@saul.com

Attorneys for Plaintiff
Shire US, Inc.

Of Counsel:

Michael F. Brockmeyer
David S. Shotlander
Amanda J. Hamilton
HAUG PARTNERS LLP
1667 K St. NW, Suite 500
Washington, DC 20006
(202) 292-1530
mbrockmeyer@haugpartners.com

Fred A. Kelly, Jr.
Joshua S. Barlow
HAUG PARTNERS LLP
One Post Office Square
Boston, MA 02109
fkelly@haugpartners.com

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SHIRE US, INC., Plaintiff, v. ALLERGAN, INC., ALLERGAN SALES, LLC, AND ALLERGAN USA, INC., Defendants.	**Civil Action No. 17-7716 (JMV)(SCM)** **Motion Date: February 20, 2018** Oral Argument Requested

MEMORANDUM IN SUPPORT OF SHIRE'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Regulations

INTRODUCTION

Allergan's use of unlawful bundled rebates and exclusive dealing has effectively excluded Xiidra® – Shire's "best-in-class" treatment for dry eye disease ("DED") – from the market for prescription drugs for the treatment of DED available to patients through Medicare Part D prescription drug plans (the "Part D market"). While those plans provide Medicare-eligible citizens with government-subsidized coverage for prescription drugs, Allergan's unlawful scheme has effectively deprived Medicare DED patients access to Xiidra. To date, Allergan has coerced Part D plans representing over 70% of the Part D market to exclude or severely restrict Xiidra on their formularies, and instead provide "preferred" formulary placement for Restasis® – Allergan's vastly inferior treatment for DED.

Allergan's goal is simple – protect Restasis's 12 year-old monopoly in the Part D market – and its unlawful tactics have been effective. Despite Restasis's clear inferiority to Xiidra, Allergan maintains a stranglehold on about 90% of the Part D market. In stark contrast, Restasis's market share in the commercial insurance market fell to about 65% within a year of Xiidra's launch.

The harm caused by Allergan's scheme is far-reaching. It has limited growth of DED prescription drugs in the Part D market. It has denied Part D patients meaningful access to a superior therapy. And, it has forced Part D patients to pay more for their DED drugs. These actions, and those described in great detail in

Shire's Complaint, harm competition in the Part D market, violate federal and state antitrust laws, injure Shire and Part D patients, and constitute tortious interference under New Jersey law.

Allergan's Motion to Dismiss nonetheless argues that:

- The Part D market for DED prescription drugs is not a plausible antitrust "relevant product market," Memorandum of Law in Support of Defendants' Motion to Dismiss ("Allergan Mem.") at 13;
- Otherwise unlawful bundling does not violate the antitrust laws if Allergan does not have monopoly power over the drugs it has bundled with Restasis, *id.* at 26;
- Allergan's exclusive dealing agreement with a major Part D plan is not unlawful because it lasts only one year, *id.* at 33;
- Allergan's unlawful bundling has not resulted in below cost prices that would support a "predatory pricing" claim, *id.* at 35; and
- Shire cannot state a claim for tortious interference under New Jersey law separate from its antitrust claims, *id.* at 39.

Allergan makes no other challenges to the sufficiency of the Complaint, and those that it does make have no support in fact or law. Indeed, Allergan has ignored Supreme Court and Third Circuit precedent, misconstrued and improperly relied upon cases from outside the Third Circuit, and sidestepped most of the Complaint's allegations.

First and foremost, Allergan's challenge to the Complaint's relevant product market definition completely ignores *Brown Shoe Co. v. U.S.*, 370 U.S. 294 (1962), a seminal decision in which the Supreme Court articulated a time-honored

framework for evaluating the "relevant product market" under antitrust law. *Id.* at 325. In simplest terms, *Brown Shoe* instructs that the boundaries of the relevant product market can be determined by considering the "practical indicia" of the market, such as market dynamics and market participant perspectives. *Id.* Here, the Complaint provides many examples of those "practical indicia" and thoroughly demonstrates that the Part D and the commercial insurance markets are separate and distinct. For example, (i) Allergan, Shire, other drug companies, Part D plans, and patients all treat the Part D and commercial markets as separate markets; (ii) Part D prescription drug coverage is subject to different and more onerous regulations with respect to content, choice, marketing, and compliance requirements for Part D plans than the commercial market; (iii) even where plans offer both Part D and commercial coverage, drug companies must negotiate separate agreements with independent rebate and other terms for placement on those plans' Part D and commercial formularies; (iv) Xiidra and Restasis have different effective prices for Part D and commercial plans; (v) Part D plans can serve only Medicare eligible patients, a restriction inapplicable to commercial plans; and (vi) by law, Part D plans use a one-year contracting cycle whereas commercial plans do not. These allegations are more than sufficient to show that the Part D market is a "relevant product market."

Second, contrary to Allergan's assertion, there is no requirement under Third

Circuit precedent that a defendant have monopoly power over the non-competing products it has bundled when it has monopoly power over the competing product. *LePage's, Inc. v. 3M*, 324 F.3d 141 (3d Cir. 2003) (decided *en banc*). Unlawful bundled pricing can exist when the only product subject to the defendant's monopoly power is the product on which the parties are competing and against which the antitrust claim is made. Unquestionably, Shire alleges that Allergan engaged in unlawful bundling.

Third, Allergan's argument that its exclusive dealing arrangements are not unlawful because its agreements with Part D plans have only a one-year term is directly contrary to Third Circuit law. *U.S. v. Dentsply Int'l, Inc.,* 399 F.3d 181 (3d Cir. 2005) (finding antitrust liability where the relevant exclusive arrangements were terminable at will). And because a major Part D plan told Shire that it could *never* displace Allergan's exclusive arrangements (whatever their claimed duration), there is no doubt that Shire has adequately pled an exclusive dealing claim.

Fourth, Allergan argues that the Complaint's bundling allegations do not show below-cost prices supporting a "predatory pricing" claim. Allergan Mem. at 35. This contention is altogether beside the point. Shire has not sought to plead a "predatory pricing" claim. Its allegations about pricing, production costs, and efficiency show that Shire is an "equally efficient competitor" that is able to meet

or beat any lawful pricing offered by Allergan.

Finally, contrary to Allergan's argument, Shire's tortious interference claims under New Jersey law do not rise or fall with its antitrust claims. Rather, they are separate claims, supported by additional allegations, that address separate harms caused by Allergan's actions.

In sum, Shire's detailed and well-pled Complaint states plausible claims against Allergan, and the Court should deny Allergan's Motion to Dismiss.

FACTUAL BACKGROUND

A. Occurrence and Treatment of DED

DED is a debilitating disease that, if left untreated, can cause permanent eye damage and vision loss. Nearly 30 million Americans suffer from DED. Because DED progresses with age, it disproportionately affects the elderly. Roughly 11% of Americans over 65 have DED, including more than 5 million Medicare beneficiaries. Compl. ¶¶ 34-37.

Until Shire launched Xiidra in August 2016, Restasis was the only prescription drug available to treat DED. Restasis is narrowly approved to treat only those patients suffering from reduced tear fluid volume, a sign of DED. Due to severe side effects and a high rate of discontinuance, many physicians also prescribe Restasis with steroids as an adjunct therapy, which increases both the price and risk of Restasis therapy. *Id.* ¶¶ 38, 40-42, 46.

Xiidra, on the other hand, is broadly approved to treat both the signs and symptoms of DED. Xiidra is more effective than Restasis, provides faster relief, requires no adjunct therapy, and has the same wholesale price. *Id*. ¶¶ 3, 44, 141.

Less than one year after its launch, Xiidra held about a 35% share of the commercial insurance market, while Restasis's share correspondingly declined to about 65%. By contrast, despite Xiidra's clinical superiority and the fact that DED disproportionately effects a higher percentage of Medicare beneficiaries, the Part D market has proven to be effectively impenetrable for Xiidra. Due to Allergan's anticompetitive actions, Xiidra's market share remains stagnant at about 10%. *Id*. ¶¶ 1, 11, 16, 79, 121.

B. The Part D Market

Medicare provides health insurance to people age 65 and older, and Part D is the subsidized prescription drug benefit under Medicare. The Centers for Medicare & Medicaid Services ("CMS") contracts with private companies, known as "Part D Plan Administrators" (referred to as "Part D plans"), to provide Part D drug coverage to Part D beneficiaries who generally pay a monthly premium and a cost-sharing amount for their prescriptions. The premiums are heavily subsidized, with about 75% paid by the government and 25% paid by the beneficiaries. In 2016, an estimated 40.8 million Medicare beneficiaries had Part D coverage. *Id*. ¶¶ 50-53.

Each Part D plan has a "formulary" that lists drugs available to its beneficiaries. A formulary typically has several pricing tiers, from "preferred" – the most favored – to "non-preferred" or "non-covered" – the least favored. Each tier has a co-payment ("co-pay") that a beneficiary pays out-of-pocket for a drug. The co-pay for non-preferred or non-covered drugs can be two to five times higher than the co-pay for preferred drugs. *Id*. ¶¶ 54-66.

Part D plans and drug companies annually negotiate financial terms to offset the cost of the plans' payments for drugs dispensed to plan beneficiaries. Major components of these negotiations include price protection,[1] discounts, and rebates off of wholesale drug prices that drug companies offer Part D plans to obtain favorable formulary placement. *Id*. ¶¶ 68-70.

All market participants – drug companies, insurance plans, the government, and patients – recognize the Part D market as its own market, separate and distinct from the commercial market. *Id*. ¶¶ 84, 85, 114-119.

C. Allergan Excludes Shire from Major Part D Plans

About 40% of DED drug prescriptions in the U.S. are covered by Part D plans, and favorable Part D formulary placement is critical to a DED drug's success. Restasis is one of many Allergan drugs listed on Part D plan formularies

[1] "Price protection" is a discount in the form of rebates a drug company pays to a plan to offset any increase to a drug's wholesale price during a plan's formulary period. *See* Compl. ¶ 70.

("Allergan's Part D product portfolio"). Among them are three glaucoma drugs that generate over $750 million in annual sales that Allergan can leverage to provide discounts, rebates, and other financial incentives to Part D plans to induce them to afford Restasis a preferred formulary position. *Id*. ¶¶ 58, 73-78.

Three major Part D plan administrators – Plan 1, Plan 2, and Plan 3 – together control approximately 70% of the Part D market for DED drugs. Shire negotiated with all of them in 2017 for placement of Xiidra on their formularies. *Id*. ¶¶ 88-112.

Shire offered Plan 1, which is responsible for nearly 25% of DED drug prescriptions under Part D, substantial rebates and discounts on Xiidra in exchange for placement on any formulary tier. Nevertheless, the Plan told Shire that placing Xiidra on its formulary without Allergan's permission would result in loss of its rebates on all Allergan products. When Shire offered to pay even higher rebates and steeper discounts, it was told in no uncertain terms "[y]ou could give [Xiidra] to us for free, and the numbers still wouldn't work." *Id*. ¶¶ 88-90.

Plan 2 is responsible for over 11% of DED drug prescriptions under Part D, and Shire's negotiations with Plan 2 bore a striking resemblance to its negotiations with Plan 1. First, Shire offered Plan 2 substantial rebates and discounts on Xiidra in exchange for a listing on its formulary. Then, Plan 2 told Shire that it would lose price protection and bundled rebates from Allergan if it placed any DED drug other

than Restasis on its formulary without Allergan's permission. Finally, when Shire offered Plan 2 even better rebate and discount terms, Plan 2 said that Shire could not pay it enough in rebates to overcome the loss of the Allergan price protection and rebates. *Id*. ¶¶ 92-94.

Allergan's agreements with Plan 1 and Plan 2 provide for price protection, substantial bundled rebates, and discounts across its Part D product portfolio, all of which would be lost if either plan put Xiidra on its formulary as anything other than a "non-preferred" drug at the highest co-payment level. Shire is an equally efficient competitor to Allergan, and Xiidra can effectively compete with Restasis in the absence of Allergan's anticompetitive conduct, as Xiidra's success in the commercial market demonstrates. Allergan's bundled discounts and rebates to Part D plans are so substantial, however, that plans have told Shire it is impossible for it to gain formulary access for Xiidra, no matter what financial terms Shire offers – even giving Xiidra to the plans "for free." *Id*. ¶¶ 9, 15, 78, 88-97, 107-08, 139-44.

Plan 3 is an administrator that negotiates formulary placement for four separate Part D plans that collectively represent over 34% of DED prescriptions under Part D. Shire offered Plan 3 substantial discounts and rebates on Xiidra in exchange for parity with Restasis on the Plan's formularies. In response, Plan 3 first said that it was interested only in "an exclusive listing" for Xiidra on its formularies, which prompted Shire to offer even more substantial discounts and

rebates. After Shire made this more favorable offer, Plan 3 assured Shire that Xiidra would be placed on the Plan's formularies. Despite this assurance, however, after speaking with Allergan, Plan 3 did an about-face, and told Shire that it would not add Xiidra to its formularies on any tier. Plan 3 gave Shire no valid reason for its newfound refusal to deal. When a Shire executive asked why, he was told that Allergan's contract with the Plan would not allow Xiidra or any other DED treatment on the formularies. Shire then asked "how do we get out of this" position in the future. The Plan replied "you don't." *Id*. ¶¶ 98-102.

Because of their bundling and exclusive dealing agreements with Allergan, Plans 1, 2, and 3 have effectively excluded Xiidra from their formularies. For patients to have access to Xiidra, they must first try and fail on Restasis and then pursue an appeal process with the Plans. Even if the appeal is successful, patients will still have to pay a co-pay that is ***two to five times higher*** than what they would have to pay for Restasis. Allergan's bundled discounts and exclusive dealing arrangements with these three Plans have, at a minimum, foreclosed Xiidra from 70% of the Part D market. Indeed, as long as these artificial barriers to patient access exist, Xiidra's market share on Part D plans will remain stagnant in the high single- or low double-digits. *Id*. ¶¶ 1, 61-66, 90-91, 95-97, 103-104, 109, 124, 129.

Allergan's monopolistic conduct threatened injury to, and is now injuring,[2]

[2] Allergan's contracts with the Plans took effect on January 1, 2018. Compl. ¶ 68.

patients covered by Part D. The exclusion of Xiidra will cause those patients to take an inferior drug to treat their DED and incur higher drug costs to do so. Shire was also threatened with, and is now suffering, substantial injury from Allergan's anticompetitive conduct because of Shire's exclusion from the Part D market. *Id*. ¶¶ 40-47, 128, 136.

STANDARD OF REVIEW

When deciding a Rule 12(b)(6) motion, the court must view the complaint in the light most favorable to the non-moving party, and draw all inferences in the non-movant's favor. *McTernan v. City of York*, 577 F.3d 521, 526 (3d Cir. 2009). At this early stage, a plaintiff needs only to allege sufficient factual matter, accepted as true "to state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 570 (2007). Plausible factual allegations "raise a right to relief above the speculative level." *Id.* at 555. "A plaintiff need only . . . raise a reasonable expectation that discovery will reveal evidence of the necessary element[s]." *Thompson v. Real Mortg. Network*, 748 F.3d 142, 147 (3d Cir. 2014).

When determining whether antitrust liability arises, "courts must look to the monopolist's conduct taken as a whole rather than considering each aspect in isolation." *LePage's,* 324 F.3d at 162 (citing *Cont'l Ore Co. v. Union Carbide & Carbon Corp.,* 370 U.S. 690, 699 (1962) ("In cases such as this, plaintiffs should be given the full benefit of their proof without tightly compartmentalizing the

various factual components and wiping the slate clean after scrutiny of each.")); *see also In re Gabapentin Patent Litig.*, 649 F. Supp. 2d 340, 359 (D.N.J. 2009) ("If a plaintiff can allege that a series of actions, when viewed together, were taken in furtherance and as an integral part of a plan to violate the antitrust laws, that series of actions, as an overall scheme, may trigger antitrust liability.").

ARGUMENT

I. Shire Plausibly Alleges a Relevant Product Market of Prescription Drugs for the Treatment of DED Available Through Medicare Part D

It is well-settled that "[t]he outer boundaries of a product market are determined by the reasonable interchangeability of use or the cross-elasticity of demand between the product itself and substitutes for it." *Brown Shoe*, 370 U.S. at 325. The Supreme Court also made clear that within a "broad market" (*e.g.*, the U.S. market for prescription DED medications), "well-defined submarkets may exist which, in themselves, constitute product markets for antitrust purposes." *Id.* Under *Brown Shoe*, the boundaries of a relevant product market are set by examining "practical indicia" such as "industry or public recognition of the submarket as a separate economic entity, the product's peculiar characteristics and uses…distinct customers, distinct prices, sensitivity to price changes, and specialized vendors." *Id*. Put another way, "market definition 'must take into account the realities of competition.'" *U.S. v. Aetna, Inc.*, 240 F. Supp. 3d 1, 21 (D.D.C. 2017) (internal citations omitted).

By its very nature, the assessment of the relevant product market poses a highly fact-intensive inquiry that is "best allocated to the trier of fact." *In re Ductile Iron Pipe Fittings (DIPF) Direct Purchaser Antitrust Litig.*, No. 12-711, 2013 WL 812143, at *15 (D.N.J. Mar. 5, 2013); *Fineman v. Armstrong World Indus., Inc.*, 980 F.2d 171, 199 (3d Cir. 1992). The defendant's business records, which are rarely available to the plaintiff at the motion to dismiss stage (as is the case here), are often critical to evaluate the issue. *Aetna,* 240 F. Supp. 3d at 21 (business records define the "contours of competition from the perspective of the parties") (citing *U.S. v. H&R Block*, 833 F. Supp. 2d 36, 52 (D.D.C. 2011)). As with any other element of a claim, a plaintiff "need only put forth allegations that raise a reasonable expectation that discovery will reveal evidence of [that] element." *Thompson*, 748 F.3d at 147 (internal quotations omitted). Dismissal at the pleadings stage is appropriate only when a defendant can establish that the alleged relevant market is "inherently implausible." *GN Netcom, Inc. v. Plantronics, Inc.*, 967 F. Supp. 2d 1082, 1087 (D. Del. 2013) ("Absent an inherently implausible market allegation, the question must be resolved on the facts and economic realities of the case.").

Shire's Complaint sets forth in detail "practical indicia" that show that the relevant market is properly defined as the market for prescription drugs for the treatment of DED available under Part D plans. And even without access to

Allergan's business records, the Complaint unquestionably raises a "reasonable expectation" that discovery will reveal evidence supporting its allegations.

Conversely, Allergan has not and cannot establish that it is "inherently implausible" that the Part D market is the relevant product market. Its assertions that the relevant market can be assessed only from the perspective of the supplier – and that Shire has failed to do so – ignore the allegations of the Complaint and rely on cases that are inapposite and readily distinguishable.

A. Shire's Allegations Plausibly Establish that the Part D Market is the Relevant Product Market

Because the Complaint alleges injury to Shire, as well as Part D patients, Shire has defined the relevant product market from the perspectives of both DED suppliers and Part D patients. Shire's allegations detail how and why patients and suppliers view the Part D market as separate and distinct from the commercial insurance market and act accordingly. Because commercial plans and patients are not interchangeable with Part D plans and patients, the "relevant product market" within which to evaluate Allergan's conduct is the Part D market. ¶¶ 84, 85, 114-119.

Allergan asserts that Shire's alleged relevant product market is implausible because it is limited to Part D plans and excludes commercial insurance. Allergan Mem. at 14. Specifically, Allergan relies on Shire's allegation that patients covered by Part D do not view commercial coverage as a substitute for Part D coverage to

argue that Shire has failed to define the relevant product market from the perspective of the supplier. *Id*. at 22 (quoting Compl. ¶ 116). But this allegation does not undermine the plausibility of Shire's market definition; it supports Shire's claim that Allergan's unlawful conduct harms Part D patients, causing Shire to describe and define the relevant product market from their perspective. Allergan has not addressed the issue of patient harm, or argued that the market cannot be defined from the patient perspective if there is patient harm.

Allergan completely ignores the Complaint's detailed allegations describing the Part D market from the supplier's perspective, which show that drug companies and Part D plan administrators view the Part D market as a market separate from commercial insurance, and operate accordingly. Specifically:

- Allergan itself views Part D as a separate market.
    - Allergan's CEO, Brett Saunders, boasted to investors that Allergan has "blocked" Shire from the Part D market. Compl. ¶ 84.
    - In a Q1 2017 earnings call, Chief Commercial Officer and Executive Vice President, William Meury stated:

> As it relates to formulary coverage, roughly 40% of Restasis and other dry eye products will run through Medicare Part D. And today, we have 95% coverage . . . my sense is that once we complete negotiations for Part D, the picture in '18 is going to look comparable and as good as 2017. And so we're exactly where we want to be as it relates to Restasis.

Id. ¶ 85.

- Allergan, Shire, and other industry participants recognize Part D drug

plans to be distinct from commercial drug plans. *Id*. ¶ 117.

- Drug companies' Part D businesses are subject to different statutes[3] and regulations as compared to their commercial businesses, prohibiting certain practices and imposing reporting requirements. *See, e.g.*, CMS Medicare Prescription Drug Benefit Manual, Ch. 6, §§ 10.2 ("Covered Part D Drug"), 20.1 ("Excluded Categories"), and 30.1.1 ("Membership [on P&T Committees]") (available at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf).

- To comply with these statues and regulations, drug companies separate their Part D and commercial businesses. They often use different staff, or hire a third party, to negotiate with Part D plan administrators even though many of those administrators also manage commercial formularies. Compl. ¶ 117.

- The Part D contracting cycle is different from commercial plans. To gain access to Part D formularies, drug companies begin negotiations with plans in or around April ending in August to allow time for CMS review and approval, whereas commercial plans are open to negotiations all year and there is no CMS role. *Id*. ¶ 118.

- Pharmaceutical companies separately monitor and report their Part D sales and financial performance. *Id.* ¶ 118.

- Pharmaceutical companies have different pricing for Part D plans than commercial insurance plans. For example, drug companies typically give deeper rebates and more attractive price protection terms to Part D plans compared with commercial plans. *Id*. ¶¶ 15, 119.

- Many of these differences are also true for Part D plans themselves.

[3] As but one example, dealing with Part D plans poses risk for drug companies under the Anti-Kickback Statute and other federal statutes. *See, e.g.* CMS Medicare Prescription Drug Benefit Manual, Ch. 1, § 40 ("Financial Relationships Between PDP Sponsors, Health Care Professionals, and Pharmaceutical Manufacturers") (available at https://www.cms.gov/Medicare/Prescription-DrugCoverage/PrescriptionDrugCovContra/Downloads/Chapter1.pdf). Dealing with commercial plans presents no such risks.

Taken as a whole, Part D plans keep their Medicare businesses separate from their commercial businesses, and separately monitor and report their Part D sales and financial performance. In particular, the rebates offered and paid to commercial plans and Part D plans must be distinct, and commercial plans are unable to leverage Part D plan rebates to negotiate a better deal for themselves with drug companies. *Id*. ¶ 119.

- Part D is subject to thousands of pages of federal regulatory requirements on choice, content, marketing, and compliance inapplicable to the commercial market. *Id*. ¶ 54, 42; CFR § 423.1, *et seq*. (2014).

These allegations identify precisely the type of "practical indicia" that *Brown Shoe* highlights – "industry and public recognition" of the market as a "separate economic entity…distinct customers, distinct prices, and specialized vendors" – and plausibly establish that the Part D market is the appropriate relevant product market here. *Brown Shoe*, 370 U.S. at 325.

B. Allergan's Misplaced Reliance on Excluded Provider Cases

In the face of Shire's thorough and well-pleaded factual allegations regarding the "practical indicia" of the Part D market, Allergan relies on several health care provider cases, which it claims mandate that the market be defined solely from the perspective of the supplier. Allergan's reliance on those cases is misplaced for two reasons.

First, unlike Shire, the plaintiffs in those cases defined the relevant market in very narrow terms and did not make adequate allegations about the market from the supplier perspective. *See Little Rock Cardiology Clinic PA v. Baptist Health*, 591 F.3d 591, 597 (8th Cir. 2009) (rejecting plaintiff's relevant product market

because allegations support only the consumer's perspective and not the supplier's); *Campfield v. State Farm Mut. Auto. Ins. Co.*, 532 F.3d 1111, 1119 (10th Cir. 2008) (finding that plaintiffs provide no explanation as to why the court should not consider alternative buyers); *Stewart v. Gogo, Inc.*, No. C-12-5164, 2013 WL 1501484, at *4 (N.D. Cal. Apr. 10, 2013) (finding that the plaintiffs did not allege any facts to support a narrower market); *Marion Healthcare LLC v. Southern Illinois Healthcare*, No. 12-CV-0871, 2013 WL 4510168 (S.D. Ill. Aug. 26, 2013) (allegation that government payments to health care providers were less than commercial insurance payments, without more, did not limit a relevant product market to commercial insurance). In stark contrast, as discussed above, *see* pp. 15-17, *infra.*, Shire's Complaint details at great length the supplier's perspective of Part D – including Allergan's own perspective – and why Part D is a relevant product market from that perspective.

Second, unlike Shire, the plaintiffs in the "excluded supplier" cases only alleged injury to themselves and did not allege any injury to consumers – *i.e.*, patients. *See, e.g.*, *Little Rock Cardiology*, 591 F.3d at 597 ("LRCC's claims boil down to the allegation that, due to Baptist Health's allegedly unlawful actions, LRCC has access to fewer patients."); *Colonial Medical Group, Inc. v. Catholic Healthcare West*, No. C-09-2192, 2010 WL 2108123, at *6 (N.D. Cal. May 25, 2010) (plaintiff only alleges harm to medical providers and does not allege harm to

any consumer other than the CA Dept. of Corrections); *see also Campfield v. State Farm Mut. Auto. Ins. Co.*, 532 F.3d 1111, 1118 (10th Cir. 2008) (plaintiff only alleged harm to itself); *Brokerage Concepts, Inc. v. U.S. Healthcare, Inc.*, 140 F.3d 494, 519 (3d Cir. 1998) ("[T]he only evidence of harm to competition was that [the plaintiff, a third-party health plan administrator,] failed to renew one contract.").

Shire, on the other hand, alleges that Allergan's scheme injures not only Shire, but Part D patients as well. It deprives them of a superior DED drug and costs them more money due to the need, in many cases, to use an adjunct therapy with Restasis that is not needed with Xiidra and because Part D patients will pay vastly higher co-pays for Xiidra if they are able to successfully appeal for coverage with Part D plans. Compl. ¶¶ 128-136. Moreover, patients would not, and in most cases could not, look to commercial insurance as an alternative to avoid the harm caused to them by Allergan's anticompetitive scheme. Thus, Shire's allegations establish that there is a meaningful distinction between the Part D and commercial markets from a patient's perspective.

Finally, *Brokerage Concepts*, which Allergan also relies upon, provides no support for Allergan's argument. First and foremost, the plaintiff in that case defined the relevant market in narrow terms – a single, private insurer. Moreover, the decision cited by Allergan addressed issues the parties raised after trial, not in a motion to dismiss. Indeed, when the defendant previously raised its market

definition arguments in its motion to dismiss, the district court rejected them and allowed the case to proceed. *Brokerage Concepts, Inc. v. U.S. Healthcare, Inc.*, No. 95-1698, 1995 WL 455969, at *4 (E.D. Pa. July 27, 1995) ("Plaintiff is entitled the opportunity to use discovery to develop such a record in support of its claim, as well as to refine its allegations as to the relevant product and geographic markets."); *see also In re Fasteners Antitrust Litig.*, No. 08-MD-1912, 2011 WL 3563989, at *10 (E.D. Pa. Aug. 12, 2011) (plaintiff not required to plead the precise boundaries of a product market prior to discovery).

In sum, Shire's Complaint sets forth detailed allegations about the "practical indicia" of the Part D market from the perspective of both suppliers and patients that are more than sufficient to support Shire's relevant product market definition. As a result, Allergan has not met its burden of establishing that Shire's alleged relevant product market is "inherently implausible," and its Motion should be denied.

C. Patients Covered by Commercial Health Plans Are Not in the Relevant Product Market

Allergan next argues that the relevant product market should be defined by identifying "the full range of sell opportunities reasonably open to" Shire, which includes "sales to patients with commercial health plans." Allergan Mem. at 23 (internal citations omitted). This argument is also without merit for several reasons.

First, simply because patients with commercial insurance plans are

"reasonably open" to Shire does not mean that those patients should be included in the same relevant product market as Part D patients. *See Aetna*, 240 F. Supp. 3d at 20 (two products are not in the same relevant product market merely because they are functionally interchangeable – *i.e.*, can be used for the same purpose as the product at issue). Under the *Brown Shoe* "practical indicia" framework, the relevant product market inquiry turns instead on whether suppliers view patients insured under Part D plans and patients insured under commercial plans to be reasonably interchangeable. *See* 370 U.S. at 325. As discussed above, they do not. All of the market participants in the Part D market – drug companies (including Allergan), insurers, the government, and patients – view the Part D market as a separate market and behave accordingly. Compl. ¶¶ 12, 37, 53, 55, 57, 68, 71-72, 83-85, 114-119.

Second, regardless of how Allergan characterizes Shire's allegation that "Xiidra has successfully captured approximately a 35% market share with commercial plans nine months post launch," *id*. ¶ 121, that allegation does not help Allergan's argument. The fact that Shire has captured 35% of the commercial market while at the same time it has been limited to only 10% of the Part D market due to Allergan's anticompetitive conduct and – despite offering better and more aggressive commercial terms to the Part D plans – is even further proof that the two markets are separate. If the two markets were interchangeable, then Allergan's

anticompetitive conduct would not matter.

D. Shire Need Not Plead that Sales to Part D Patients are Essential to Shire's Survival

Allergan asserts that Shire's relevant product market allegations can survive only if Shire has alleged that "sales to patients with Medicare Part D plans are essential or critical for Shire's survival in the market." Allergan Mem. at 24 (citing *Methodist Health Serv. Corp. v. OSF Healthcare Sys.*, No. 13-01054, 2015 WL 1399229 (C.D. Ill. Mar. 25, 2015)). That is not the law, and the importance of Part D to Shire's survival has no connection whatsoever to Shire's relevant product market allegations.

In support of its argument, Allergan cites to one decision in the *Methodist Health* case and disregards another. The decision that Allergan disregards is a decision on the defendant's motion for summary judgement. There, the court distinguished *Little Rock Cardiology,* cited to *Brown Shoe*, and upheld plaintiff's relevant market definition separating commercial insurers from government insurers because the plaintiff had presented evidence showing that government and commercial health insurers are not reasonably interchangeable from the supplier's perspective. *Methodist Health*, 2016 WL 5817176, at *9 (C.D. Ill. Sept. 30, 2016).

The decision that Allergan cites is an earlier decision on the defendant's motion for judgment on the pleadings. There, the court denied defendant's Rule 12(c) motion, finding that the plaintiff had plausibly alleged a relevant product

market for commercial health plans because "the Court cannot find, as a matter of law, that the sales of inpatient hospital and outpatient surgical services to commercial health insurers are interchangeable with the sales of these same services to government payers." *Id.* at *7. While the court also referred to an allegation that access to privately-insured patients was critical to the provider's long-term sustainability, that allegation was not the foundation of its ruling. *Id.* More importantly, whatever marginal significance the *Methodist Health* court may have placed on the provider's long-term sustainability in its evaluation of the relevant product market allegations when ruling on the 12(c) motion, it did not even mention long-term sustainability in its summary judgment decision.

Thus, *Methodist Health* provides no support for Allergan's contention. To the contrary, read together and in context, the district court's decisions fully support Shire's alleged Part D market, without regard to whether that market is critical to Shire's sustainability.

E. *U.S. v. Aetna* Supports Shire's Relevant Product Market Allegations

Shire's Part D market definition is also fully supported by *Aetna*, 240 F. Supp. 3d 1, which found that Medicare Advantage patients constitute a relevant product market separate from original Medicare. There, the Justice Department sued to block Aetna's acquisition of Humana, alleging that the merger would substantially lessen competition for Medicare Advantage policies. *Id.* at 8, 19. The

district court applied *Brown Shoe* and concluded that practical indicia showed that Medicare Advantage is a relevant product market separate from original Medicare (Part A and Part B) because:

- Medicare Advantage offers a discrete, limited network of options;
- the healthcare industry and public recognize it as a distinct market;
- Aetna and Humana report Medicare Advantage results separately and utilize different employees for their Medicare Advantage business;
- Aetna and Humana do not consider traditional Medicare pricing when setting Medicare Advantage pricing;
- Aetna and Humana assess competition among and between Medicare Advantage plans; and
- Medicare Advantage (and traditional Medicare) patients are distinct groups and rarely switch from one to another.

Id. at 23-28. Many of these "practical indicia" – from the perspective of Medicare Advantage suppliers – are substantially the same as those Shire has alleged. This further supports Shire's allegation that the Part D market is separate from the commercial market, and is the relevant product market to be considered here.[4]

II. Allergan is Engaged in Unlawful Bundling

Allergan indisputably has monopoly power over Restasis in the Part D market. Allergan has offered rebates and price protection to Plans 1 and 2 that are

[4] It is worth noting that Shire makes its allegations without the benefit of Allergan's "ordinary course documents," which were critical to the *Aetna* court's analysis because they "reveal the contours of competition from the perspective of the parties." *Id*. (citations omitted).

bundled across Restasis and other drugs in its Part D product portfolio, including three Allergan glaucoma drugs. Compl. ¶ 108. Those bundled rebates and pricing terms are conditioned on the commitment of Plans 1 and 2 not to list Xiidra on their Part D formularies or alternatively, placing Xiidra in a non-preferred formulary position. *Id.* ¶¶ 91, 97. Shire lacks a comparable Part D portfolio and cannot offer comparable bundled rebates to the Plans. *Id.* ¶¶ 91, 97, 102, 106, 108. Consequently, even if Shire gave Xiidra to the Plans "for free," that would still not make them "whole" after accounting for the loss of the aggregate amount of Allergan's bundled discounts. *Id*. ¶ 15, 86. Under Third Circuit precedent, these allegations show that Allergan is engaged in unlawful bundling that clearly violates antitrust law.

An antitrust "bundling" claim exists when: (1) two firms are competing for sales of a common product (the "overlap product"), and one of the firms (the "bundling firm") conditions discounts on both the overlap product and other products not sold by the other firm ("non-overlap products") on the buyer's purchase of the overlap product from the bundling firm; (2) the bundling firm has monopoly power in either (or both) of the market for the overlap product or the market(s) for the non-overlap products; and (3) the effect of the bundling is anticompetitive because it excludes an "equally efficient" competitor in the overlap product market. *LePage's*, 324 F.3d at 155 ("The principal anticompetitive effect

of bundled rebates as offered by 3M is that when offered by a monopolist they may foreclose portions of the market to a potential competitor who does not manufacture an equally diverse group of products and who therefore cannot make a comparable offer"); *SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056, 1065 (3d Cir. 1978).

Shire's allegations satisfy these elements. First, with Restasis, Allergan possesses monopoly power over prescription DED drugs in the Part D market, the overlap product market. Compl. ¶ 113. Second, placing Restasis on formulary is essential to the Plans to avoid the loss of Allergan's bundled discounts. *Id*. ¶¶ 89, 93. Third, even though Shire is an equally efficient competitor to Allergan, Shire is still unable to compensate a plan for its loss of Allergan's bundled discounts if the plan places Xiidra on its formulary to the disadvantage of Restasis. *Id*. ¶¶ 15, 139, 144. This bundled discounting anticompetitively excludes Xiidra, a superior drug, from the Part D market, giving Restasis unwarranted protection from competition and maintaining its monopoly. *Id*. ¶¶ 108-112.

Allergan's sole basis for seeking dismissal of Shire's bundling claims is that they are legally inadequate because Shire does not, and cannot, plead that Allergan possesses monopoly power in the market for the non-overlap products, its

glaucoma drugs.[5] Put differently, Allergan claims that bundling is actionable under the antitrust laws only when the bundling firm possesses monopoly power in the market for the non-overlap products. Allergan Mem. at 27-30. This argument simply has no basis in the Third Circuit under *LePage's* or *SmithKline*, and Allergan has cited no other case supporting it.

In *LePage's*, 3M had monopoly power in the overlap product market of transparent tape, and countered the competitive threat posed by LePage's transparent tape by anticompetitively bundling discounts on 3M's transparent tape with discounts on purchases across six diverse 3M product lines. *LePage's*, 324 F.3d at 154. In affirming the jury's finding of monopolization, the Third Circuit never said that 3M had – or needed – monopoly power in the markets for other product lines. *See id.* at 154-57. It found 3M's abuse of monopoly power to exist

[5] Through its Exhibits A-D, Allergan asks the Court to take judicial notice of facts outside the pleadings to show (i) that Shire could have, but did not, bundle Xiidra with other drugs, and (ii) that the market for glaucoma drugs is competitive. Allergan Mem. at 10, 31. This request should be denied. First, the alleged facts are irrelevant to Shire's unlawful bundling claim. Compl. ¶ 15,108; *LePage's*, 324 F.3d at 155 ("even an equally efficient rival may find it impossible to compensate for lost discounts on products that it does not produce") (internal quotation omitted). Second, the alleged facts cannot be used to show that Shire could have offered specific bundles to the Plans, or for any other purpose. *See U.S. ex. rel. Spay v. CVS Caremark Corp.*, 913 F. Supp. 2d 125, 139 (E.D. Pa. 2012) ("[Judicial] notice serves only to indicate what was in the public realm at the time, ***not whether the contents of those documents are true.***") (emphasis added). Third, the Court should not consider facts that are not – and cannot be – properly before it on a Rule 12(b)(6) motion. Thus, the law governing Rule 12(b)(6) motions and the use of judicially noticed materials require the Court to ignore these materials.

only in the overlap product market – transparent tape. *Id.* at 157 ("The jury could reasonably find that 3M used its monopoly in transparent tape, backed by its considerable catalog of products, to squeeze out LePage's."). The threat to transparent tape customers of losing discounts on the non-overlap products was enough for them to stop buying from LePage's without regard to whether 3M had monopoly power on any of the non-overlap products.

Indeed, in *Castro v. Sanofi Pasteur Inc.*, No. 11-7178, 2012 WL 12516572 (D.N.J. Aug. 6, 2012), also a bundling case, Judge Linares rejected Sanofi's attempt, similar to Allergan's here, to impose "requirements" on the allegations that must be pled as to the non-overlap products. *Id.* at *8-10. Setting aside Sanofi's arguments, Judge Linares concluded that Castro had sufficiently alleged that Sanofi had exploited its monopoly power to reduce competition in the relevant market. *Id*. at *8. Nowhere in the decision did Judge Linares hold that, to state a bundling claim, the bundling firm must have monopoly power in the non-overlap product market(s) or that the overlap product of the bundling firm must be "indispensable" to customers. Rather, he explained that "a monopolization claim is a 'highly fact-specific' exercise where the fact-finder ultimately will be required to look at a monopolist's conduct as a whole and determine whether it exploited its power and 'utilized its size for abuse.'" *Id.* at *8 (quoting *Race Tires Am. Inc. v. Hoosier Racing Tire Corp.*, 614 F.3d 57, 80 (3d Cir. 2010) and *LePage's*, 324 F.3d

at 148, 158, 162). Expanding on this, Judge Linares stated:

> Contrary to Sanofi's various attempts to craft specific dispositive requirements from various antitrust cases, the Third Circuit noted in *LePage's* that there is no clear formula for what is unlawful anticompetitive behavior. And behavior that may be acceptable for one business or in one context may violate antitrust laws when engaged in by a monopolist.

Sanofi, 2012 WL 12516572, at *8 (internal citations omitted). This is entirely consistent with the law of the Third Circuit.

Moreover, none of the cases cited by Allergan supports its position. While Allergan cites the *SmithKline* decision, the Third Circuit did not say in that case (as Allergan claims), or later in *LePage's*, that monopoly power in the non-overlap product market versus the overlap product market was the *sine qua non* for SmithKline's bundling claim. *See SmithKline*, 575 F.2d at 1065.

Allergan also attempts to rely upon *dicta*[6] in *Masimo Corp. v. Tyco Health Care Group, L.P.*, No. 02-4770, 2006 WL 1236666, at *12 (C.D. Cal. Mar. 22, 2006). In the first instance, this Court should disregard *Masimo* because, as part of its *dicta*, the *Masimo* court expressly "disagree[d] with the reasoning of the *LePage's* and *SmithKline* opinions," *id.* at *13, which, of course, are binding precedent in this case. Second, contrary to Allergan's attempted use of the case, the

[6] The *Masimo* opinion addresses post-trial motions. Prior to the discussion cited by Allergan, the court had ruled that the plaintiff had failed to present sufficient evidence to the jury "to permit it to reach any reasonable conclusion about the anticompetitive effect of Tyco's bundling practices." *Id.* at *9, *12.

Masimo court did not say that monopoly power in the market for the non-overlap products was a prerequisite for a claim under *LePage's*. In fact, the court's discussion of *LePage's* makes absolutely no mention of the other products 3M had included in its unlawful bundle, and the court specifically referenced the overlap product (transparent tape) as the source of 3M's monopoly power underlying its unlawful bundling scheme. *Id.* at *12.

The same is true of *Virgin Atlantic Airways v. British Airways plc.*, 257 F.3d 256, 270 (2d Cir. 2001), which Allergan also cites. There, the Second Circuit distinguished *LePage's* as a case "where the plaintiff introduced exhibits showing that specific customers felt compelled to purchase products under the defendant's bundling program because the plaintiff could not match the discounts." *Id*. Nowhere did the Second Circuit say that a viable bundling claim requires that the defendant have monopoly power in the market for the non-overlap products.

Simply stated, Allergan argues for a legal requirement – the bundling firm's monopoly power over the non-overlap products – that has no legal foundation. The Third Circuit has not imposed such a requirement, and no other case Allergan cites outside the Third Circuit has either.

III. Allergan's Exclusive Dealing Arrangement With Plan 3 is Anticompetitive

Shire alleges that: (i) Restasis's Part D market share is about 90%, (ii) Allergan's overall scheme to monopolize the Part D market includes an exclusive

dealing arrangement between Allergan and Plan 3 (which represents about 34% of all Part D patients), and (iii) Shire has been told that it will be foreclosed from future contract negotiations with Plan 3. Compl. ¶¶ 1, 23, 98-107. These allegations establish beyond question that Shire has plausibly alleged that Allergan's exclusive dealing agreement with Plan 3 is anticompetitive.

In challenging Shire's exclusive dealing claim, Allergan makes only one argument[7] – that Shire's claim is not legally viable because Allergan's agreement with Plan 3 has a term of one year and "exclusive dealing agreements lasting a year or less are not plausibly anticompetitive." Allergan Mem. at 33 (citing Compl. ¶ 68).[8]

This argument – that there is a rigid "temporal" rule that an exclusive dealing arrangement with a duration of one year or less cannot plausibly be anticompetitive – directly conflicts with controlling Third Circuit precedent (as well as precedent from other circuits). In *Dentsply*, 399 F.3d 181, the Justice Department challenged the exclusive dealing practices of a dominant firm

[7] Allergan does not argue that Shire has failed in any other way to allege that the challenged exclusive dealing arrangement substantially forecloses competition. *See Tampa Elec. Co. v. Nashville Coal Co.*, 365 U.S. 320, 334 (1961) (exclusive dealing arrangements are anticompetitive when they substantially foreclose competition).

[8] Allergan's observation that Shire also sought an exclusive formulary placement from Plan 3, Allergan Mem. at 34-35, is irrelevant because "behavior that otherwise might comply with antitrust law may be impermissibly exclusionary when practiced by a monopolist." *Dentsply*, 399 F.3d at 187.

(Dentsply) even though Dentsply's relationship with its dealers was purchase order to purchase order and "essentially [was] ***terminable at will***." *Id.* at 185 (emphasis added). Dentsply had no binding contract with dealers preventing them from doing business with Dentsply's competitors. *Id.* Nonetheless, the court concluded that Dentsply had effectively put in place unlawful exclusive dealing to exclude competitors. *Id*. at 193. In summarizing its holding, the Third Circuit stated:

> In this antitrust case we conclude that an exclusivity policy imposed by a manufacturer on its dealers violates Section 2 of the Sherman Act. We come to that position because of the nature of the relevant market and the established effectiveness of the restraint *despite the lack of long term contracts between the manufacturer and its dealers*.

Id. at 184 (emphasis added).

Other circuits have likewise refused to impose a "hard-and-fast" rule of duration in evaluating exclusive dealing claims. For example, the Eleventh Circuit in *McWane, Inc. v. FTC*, 783 F.3d 814, 833-34 (11th Cir. 2015), followed *Dentsply* and rejected a rule proposed by the defendant – "presumptive legality" of short-term, exclusive agreements – that was even less rigid than the *per se* legality rule that Allergan advocates here. There, the Eleventh Circuit explained that courts should assess the legality of exclusivity arrangements by "look[ing] at the 'practical effect' of exclusive dealing" rather than focusing on the supposed "limited temporal scope of the agreements." *Id.* at 834 (quoting *Tampa Elec.*, 365 U.S. at 326-28).

Moreover, the cases Allergan cites are readily distinguishable. In each of those cases, the critical issue for the court's dismissal of the exclusive dealing claim was not the specific length of the agreement's terms, but instead the fact that the excluded firm could once again compete when the agreements expired. *See Spinelli v. National Football League*, 96 F. Supp. 3d 81, 117 (S.D.N.Y. 2015) (finding that the "NFL 'entertained bids for exclusive commercial licensing rights for NFL and NFL Team photos' at the conclusion of each agreement's term"); *PNY Technologies, Inc. v. SanDisk Corp.,* No. 11-CV-04689, 2014 WL 2987322, at *6 (N.D. Cal. July 2, 2014) (finding that the plaintiff did not plead "facts showing that it failed to win contracts despite offering better terms or that [the defendant] somehow thwarted its efforts to secure business through conduct other than competition on the merits"); *SPX Corp. v. Mastercool U.S.A., Inc.*, No. 3:10-CV 1266, 2011 WL 2532889, at *4 (N.D. Ohio June 24, 2011) ("[N]othing prevents [the plaintiff] from competing for those distributors and servicers once the agreements expire . . . ."); *Sterling Merchandising, Inc. v. Nestle, S.A.*, 724 F. Supp. 2d 245, 265 (D.P.R. 2010) ("Any possible interruption to competition that they might cause is only for a short period after which competitors may gain entry to foreclosed outlets."); *see also Banxcorp v. Bankrate Inc.*, No. 07-3398, 2011 WL 6934836, at *20 (D.N.J. Dec. 30, 2011) (one-year contract without corresponding allegations that the defendant acted illegally does not violate

antitrust laws).

Contrary to the plaintiffs in these cases, Shire does not have the ability to compete upon the annual "expiration" of Allergan's exclusive dealing arrangement with Plan 3, as shown by the course of the parties' negotiations.

Plan 3 first told Shire that placing Xiidra on Plan 3's formularies would not be "disruptive" and that Shire's financial proposal would "get it done." Compl. ¶ 100. To be certain, Shire asked if it needed to improve its offer. *Id.* Plan 3 said no, but then consulted Allergan and reversed course. *Id.* ¶ 101. Plan 3 then rejected Shire's proposal, using the pre-textual reason that switching from Restasis to Xiidra would be disruptive, and confirmed that Plan 3's agreement with Allergan prevented Plan 3 from putting Xiidra or any other DED drug on its formulary. *Id.* ¶ 102. When Shire then asked Plan 3 how it could get out of this situation in the future, Plan 3's direct and unambiguous response was "you don't." *Id.* Put simply, after consulting with Allergan, Plan 3 essentially told Shire: don't bother bidding in the future for a formulary placement for Xiidra because Restasis will continue to be exclusive on the formulary.

The practical effect of Allergan's exclusive dealing agreement is plain. It does not matter that the Part D contracts are negotiated annually and have a one-year term. Plan 3's blunt candor to Shire makes it clear that Allergan's exclusive dealing arrangement will allow Allergan to maintain its monopoly in the market

for DED drugs available to Part D patients for the foreseeable future.

IV. Shire Plausibly Alleges an Unlawful Bundling Claim, not a Predatory Pricing Claim

Allergan argues that Shire has not plausibly alleged that its bundled discounts are anticompetitive because it has not alleged that the resulting Restasis prices to Plans 1 and 2 were "below its cost." Allergan's Mem. at 35-39. Yet again, Allergan's contention is contrary to *LePage's*. There, the Third Circuit rejected a bright-line "below cost requirement" for a bundling claim. It also ignores Shire's specific allegations that Allergan's Restasis pricing to Plans 1 and 2 is below Allergan's average variable cost taking into account the bundled rebates. Similarly, Allergan's "predatory pricing" argument is nothing more than a strawman.

Relying upon its flawed argument that Shire's bundling claim requires that Allergan have monopoly power over the bundled glaucoma drugs (the non-overlap products in the bundle), Allergan recharacterizes Shire's allegations as an impaired so-called "predatory pricing" claim. *Id*. at 36. Based on that premise, Allergan then criticizes as inadequate Shire's allegation that Restasis's pricing to the Part D plans subject to Allergan's bundled discounting is below its cost when all the bundled discounts are attributed to Restasis. *Id*. at 37.

There are at least three reasons why the Court should reject Allergan's argument. First, under *LePage's*, Allergan's bundled discounting is anticompetitive even if it does not result in below cost pricing. There, the court flatly rejected 3M's

argument, similar to Allergan's here, that so long as 3M's pricing was above cost there could be no antitrust violation. 324 F.3d at 147-52. Thus, even if Shire's allegation of below cost pricing is inadequate, which it is not, it is unnecessary to state a claim for anti-competitive bundled discounting under *LePage's*.[9]

Second, even accepting Allergan's mistaken legal premise, Shire alleges exactly what Allergan claims it does not – that the aggregate value of Allegan's bundled discounts when attributed to Restasis causes Allergan's price for Restasis to be below Allergan's average variable cost. The Complaint specifically alleges that Part D plans have told Shire that "[y]ou could give [Xiidra] to us for free, and the numbers still wouldn't work." Compl. ¶¶ 15, 89. Essentially, Part D plans have said that providing Xiidra for free still results in Xiidra being more expensive than Restasis. This is due to the Plans' loss of Allergan's bundled discounts, the aggregate value of which must result in Allergan providing Restasis at an effective price that is below Allergan's average variable cost. *Id*. ¶ 78.

Allergan and Shire are comparable companies, and Allergan does not have any advantage in size, breadth, resources, or structure enabling it to produce Restasis for less cost than Shire produces Xiidra. *Id*. ¶¶ 78, 139, 143. Thus, it is

[9] Allergan's reliance on *Cascade v. PeaceHealth*, 515 F.3d 883 (9th Cir. 2008), is unwarranted. The Ninth Circuit expressly disagreed with *LePage's* in that case. *Id.* at 903 ("[W]e decline to endorse the Third Circuit's definition of when bundled discounts constitute the exclusionary conduct proscribed by § 2 of the Sherman Act."). Because *LePage's* is binding Third Circuit precedent, the Court should disregard any discussion of *Cascade*.

reasonable to conclude that Allergan cannot make Restasis at a cost lower than Shire can make Xiidra, and, therefore, Allergan is providing Restasis to the Plans at below Allergan's average variable cost. *Id*. ¶¶ 78, 86; s*ee Inline Packaging, LLC v. Graphic Packaging Int'l, Inc.*, 164 F. Supp. 3d 1117, 1129 (D. Minn. 2016) (inferring from plaintiff's allegations "that it is more efficient" but cannot "profitably offer [the overlap product] at a price sufficiently low to compete with [bundled] discounts" that "[defendant] is selling below its cost."); *BanxCorp v. Bankrate, Inc.*, No. 07-3398, 2008 WL 5661874, at *7 (D.N.J. July 7, 2008) (finding allegations that defendants charged a price below its average variable cost and "that competitors…were forced to switch . . . to an unreasonably low and unsustainable cost-per click pricing structure" to be sufficient).

Finally, Shire has brought viable claims based upon Allergan's overall scheme involving bundled discounting and exclusive dealing, and does not seek at this time to assert a claim that Allergan has engaged in predatory pricing. Thus, the Court should disregard Allergan's argument about why Shire's allegation is insufficient to support a predatory pricing claim as no more than an exercise of "building a strawman and knocking it down." *See ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 281 (3d Cir. 2012) (rejecting defendants' predatory pricing arguments and finding that "exclusive dealing arrangements can exclude equally efficient (or potentially equally efficient) rivals, and thereby harm competition,

irrespective of below-cost pricing").

V. The Complaint Plausibly Alleges a Claim for Tortious Interference

Allergan seeks dismissal of Shire's tortious interference claim on three grounds, all of which fail. First, Allergan's choice of law argument arises solely from a misplaced application of the innocuous concept that the evaluation of a claim's compliance with *Twombly* must be preceded by a court's determination of applicable law. *See* Allergan Mem. at 39 (citing *In re Enron Corp. Sec.*, 761 F. Supp. 2d 504 (S.D. Tex. 2011)). In *Enron*, the district court simply held that it could not defer that determination and, thus, applied the law of *multiple* jurisdictions.[10] *Id*. at 543-44. Nothing about the *Enron* court's approach requires dismissal of Shire's claim. Regardless, the parties agree that New Jersey law applies to Shire's tort claim, rendering choice of law moot altogether.

Allergan's second argument – that Shire fails to adequately allege "malice" or wrongful conduct – ignores applicable New Jersey law holding that the element of "malice" "does not mean ill will, but means that harm was inflicted intentionally and without justification or excuse." *Cent. Lewmar, L.P. v. Gentilin*, No. 03-4671,

[10] Courts faced with perceived ambiguities in applicable law at the pleadings stage generally take one of the following approaches, none of which involves dismissal without any further basis. They perform a choice of law analysis (to the extent there is a true conflict of laws), *see Majdipour v. Jaguar Land Rover N. Am., LLC*, 2015 U.S. Dist. LEXIS 33377, at *19 (D.N.J. March 18, 2015), apply the laws of multiple states, *see Enron*, 761 F. Supp. 2d at 543-44, or defer the choice of law analysis until a further factual record is developed, *Lincoln Nat'l Life Ins. Co. v. Calhoun*, 596 F. Supp.2d 882 (D.N.J. 2009).

2005 U.S. Dist. LEXIS 45902, at *11-12 (D.N.J. June 1, 2005) (internal quotations omitted). Whether malice exists must be "determined on an individual basis, under a flexible standard . . . in the context of the facts presented." *Id*. That element is sufficiently pled when a defendant allegedly acted "intentionally" with "malice," and "tortiously" or "wrongfully" interfered with prospective business relations, *Northern Star Mgmt., Inc. v. Ins. Prof'ls, Inc*., No. 12-CV-3839, 2013 U.S. Dist. LEXIS 135286, at *9-10 (D.N.J. Sept. 23, 2013), which this Court recently determined included a defendant's engagement in an "'anticompetitive scheme' by entering into exclusive arrangements to restrict entry of competitors." *Fresenius Kabi USA, LLC v. Par Sterile Prods., LLC*, No. 16-4544, 2017 U.S. Dist. LEXIS 19084, at *12-13 (D.N.J. February 10, 2017). Shire pleads the same type of conduct here, alleging that Allergan tortiously cut off Shire's business dealings with Part D plans through an anticompetitive scheme, Compl. ¶¶ 1-25, 200-202, and, in doing so, Allergan acted "intentionally and wrongfully," "with malice," which was "unjustified" and "tortious." *Id*. ¶¶ 201-02, 204, 206.

Allergan's third argument – that Shire's tortious interference claim is necessarily coextensive with its antitrust causes of action – is not supported by the law. Allergan relies solely on *dicta* from *Ideal Dairy Farms, Inc. v. Farmland Dairy Farms, Inc.*, 659 A.2d 904, 935 (N.J. App. Div. 1995), a predatory pricing case, whose holding goes no further than the unremarkable conclusion that "low-

cost pricing which is neither predatory nor restrictive of competition…does not provide a basis for a claim of tortious interference [or a violation of antitrust laws].” This provides no support whatsoever for Allergan’s sweeping argument that, in the context of an antitrust case, tortious interference is merely coextensive of antitrust violations. In fact, binding precedent is to the contrary. In *Fineman v. Armstrong World Indus.*, the Third Circuit addressed similarities and differences between antitrust claims and claims for tortious interference under New Jersey law, holding that “tort and antitrust causes of action require widely divergent proofs . . . [and] vindicate widely differing policies; the first is wholly personal to the plaintiff-competitor and the second requires the plaintiff to demonstrate harm to competition at large and antitrust injury.” 980 F.2d 171, 187 (3d Cir. 1992).

Here, Shire has alleged a plausible, independent claim for tortious interference under New Jersey law, which survives Allergan’s Motion regardless of whether or not the Court dismisses Shire’s federal and state antitrust claims.

CONCLUSION

For the foregoing reasons, Shire has plausibly alleged each of its claims, and respectfully requests that the Court deny Allergan’s Motion to Dismiss.[11]

[11] Allergan’s proposed Order seeks a dismissal “with prejudice,” but Allergan neither makes reference to, nor provides any support for, such drastic relief in its Memorandum. Should the Court choose to grant any relief to Allergan, it should do so without prejudice and provide Shire with an opportunity to file an amended complaint.

Dated: January 23, 2018

Of Counsel:

Michael F. Brockmeyer
David S. Shotlander
Amanda J. Hamilton
HAUG PARTNERS LLP
1667 K St. NW, Suite 500
Washington, DC 20006
(202) 292-1530
mbrockmeyer@haugpartners.com

Fred A. Kelly, Jr.
Joshua S. Barlow
HAUG PARTNERS LLP
One Post Office Square
Boston, MA 02109
(617) 426-6800
fkelly@haugpartners.com

By: s/ Charles M. Lizza
Charles M. Lizza
William C. Baton
Elina Slavin
SAUL EWING ARNSTEIN & LEHR LLP
One Riverfront Plaza, Suite 1520
Newark, New Jersey 07102-5426
(973) 286-6700
clizza@saul.com

Attorneys for Plaintiff
Shire US, Inc.